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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,603	01/30/2001	Ralph D. Yoder	P04856US0	1713

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/772,603	Applicant(s) YODER ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 8-10 are pending.

2. In view of the amendment filed 2/12/02, the following objection and rejections remain.

3. The disclosure stands objected to because of the following informalities: (1) The numbering of claims on pages 13-14 should be on the left margin and not at the center of the page and (2) the blank "___" on page 5, line 8 needs to be filled in. Appropriated correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claim 8 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "a mammalian species" in claim 8 is indefinite and ambiguous. It is not clear which species applicants intended to claim. Further, the recitation of "and" in claim 8, line 1 is ambiguous because a mammal is more likely to have either bacterial or viral infection at any given time but not both at the same time.

Applicants' arguments filed 2/12/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) the term "mammalian species has a recognized understanding in the art and covers such species as porcine, ruminants, poultry, equine, ovine, human, dogs and cat, etc and (2) it is clear from the specification on page 5 that the IgG fraction of the present invention is effective against both bacteria and viruses.

However, the recitation of "a mammalian species" in claim 8 is indefinite and ambiguous since "a mammalian species" includes not just livestock but also whale, for example. It is not clear which species applicants intended to claim.

The recitation of "and" in claim 8, line 1 is ambiguous because a mammal is more likely to have either bacterial or viral infection at any given time but not both at the same time.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 6,096,310 (Filed April 1997, PTO 892) or US Pat No. 5,871,731 (Feb 1997, PTO 892) each in view of Kempf *et al* (Transfusion 31(5): 423-27; 1991) for the same reasons set forth in Paper No 6.

Applicants' arguments filed 2/12/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) the IgG fraction is not the same hydrolyzed, neutralized fraction defined by the claims since both the '310 patent and the '731 patent teach that the IgG (the whole molecule) can be orally fed, (2) Kempf reference does not relate the IgG fraction to oral use for virus inactivation.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., IgG fraction is acid hydrolyzed to a 55,000 MW protein prior to injection) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The '310 patent teaches a method of oral dosing of human, which is mammalian species, with isolated immunoglobulins (IgG) such as bovine gamma globulin that provides bacterial static activity for gastrointestinal bacterial overgrowth. The '310 patent further teaches the immunoglobulins are administered orally in doses between about 100 mg and about 1800 mg per day, which is sufficient to provide a dosage of 0.25 mg/ml in the mammal's gut.

The '731 patent teaches oral administration of purified immunoglobulin to human at dosages from 1 to 20 g per day for several days to weeks for treatment of chronic pain associated with bacterial exposure (See column 4, lines 36-47, in particular).

The claimed invention as recited in claims 8 differs from the reference only by the recitation of said isolated IgG fraction which is acid hydrolyzed, and has been heat treated from 15 minutes to one hour at a temperature of 35°C to 40°C and thereafter neutralized.

Kempf *et al* teach a method of preparing viral inactivated gammaglobulin (IgG) by mild acid hydrolysis at (pH 4) with HCl, heat at a temperature of 37°C and neutralized with NaOH for the production of intravenous immunoglobulin (See page 424, Virus inactivation, Fig 1, in particular). Kempft *et al* further teach that the virus titer dropped by approximately 4 orders of magnitude after incubation at pH 4 and 37°C (See Fig 1, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate immunoglobulin that has been prepared by mild acid hydrolysis and heat treated at a temperature of 35 to 40°C from 15 minutes to one hour as taught by Kempf *et al* for a method of oral dosing of immunoglobulin wherein the dosage for oral administration is sufficient to provide 0.25 mg/ml up to 5 g/day as taught by the '310 patent and the '731 patent.

One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to provide oral dosing of a mammalian species with isolated purified immunoglobulin because the '310 patent teaches oral dosing of immunoglobulin (IgG) such as bovine gamma globulin can provide bacterial static activity for gastrointestinal bacterial overgrowth (See Abstract, in particular). The '731 patent teaches oral administration of purified immunoglobulin to human at dosages from 1 to 20 g per day for several days to weeks for treatment of chronic pain associated with bacterial exposure (See column 4, lines 36-47, in particular). Kempf *et al* teach that mild acid hydrolysis at (pH 4) with HCl, heat at a temperature of 37°C and neutralized with NaOH can inactivate viral activity (viral static

activity) for the production of intravenous immunoglobulin (See page 424, Virus inactivation, Fig 1, in particular).

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
May 6, 2002

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